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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/854,825	05/12/1997	FRANCIS V. CHISARI	329368-101CO	9805

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/03/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/854,825

Applicant(s)

CHISARI ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Office Action

Continued Prosecution Application

1. The request filed on 11 June, 2002, for a Continued Prosecution Application (CPA) under 37 C.F.R. § 1.53(d) based on parent Application No. 08/854,825 is acceptable and a CPA has been established.

Status of the Claims

2. Acknowledgement is hereby made of receipt and entry of the amendment filed 11 June, 2002, wherein claims 22-25, 30, 32, 36, 40, and 44-66 were deleted without prejudice or disclaimer and new claims 67-97 submitted.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 67-97 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are directed toward HCV CTL epitopes carrying one to two amino acid additions, deletions, or substitutions. Immunogenic and

pharmaceutical compositions comprising the claimed peptides, as well as, various methods of use are also claimed. Additional embodiments are also directed toward conjugates comprising the peptides of interest.

5 The written description requirement under Section 112, first paragraph, stipulates that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have decided that the specification must demonstrate
10 that the inventor had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, nonetheless, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *Ralston Purina Company v. Far-Mar-Co., Inc.*, 227 U.S.P.Q. 177 (C.A.F.C. 1985). *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Blaser, Germscheid, and Worms*, 194 U.S.P.Q. 122 (C.C.P.A. 1977). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709
20 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). *In re Deuel*, 34
25 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995). Moreover, the courts have decided repeatedly that the inventor must clearly and unambiguously identify the salient characteristics and properties of any given claimed chemical compound, particularly as it applied to nucleic acids and peptides (*University of California v. Eli Lilly*, 119 F.3d
30 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991);

Fiers v. Sugano, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993); *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993); *In re Deuel*, 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995)). Thus, it is not sufficient to simply provide a vague reference to the biological activity of any given amino acid sequence or some generic method of obtaining it.

However, the skilled artisan, upon perusal of the disclosure would not accept the finding that applicants were in possession of the various peptidic variants currently encompassed by the claim language. The disclosure provides a small number of well-characterized HCV CTL epitopes (e.g., see SEQ ID NOS.: 1-3, 26, 34, 35, and 42). However, there are a number of deficiencies that clearly fail to place the applicants in possession of the claimed peptidic variants. First, the disclosure fails to provide sufficient guidance pertaining to the molecular determinants modulating the CTL-like properties of any given peptide. The disclosure fails to identify those portions of any given peptide that are critical for the retention of HCV CTL activity. Second, the disclosure fails to provide sufficient guidance pertaining to acceptable amino acid additions, substitutions, and deletions that will result in retention of the desired HCV CTL epitope. Thus, it is not clear from reviewing the specification which of the many possible amino acid changes are acceptable. Third, the prior art teaches that single amino acid changes, as well as, the addition or deletion of flanking regions, can influence the immunological properties of any given CTL epitope in an unpredictable manner (Smith et al., 1997; Bertoletti et al., 1994; Johnson et al., 1992; Couilllin et al., 1995; and, Hahn et al., 1992; Del Val et al., 1991; Hahn et al., 1992; and, Eisenlohr et al., 1992). Moreover, as previously noted, the art teaches that the mere presence of an MHC class I binding motif in a peptide is not sufficient to confer binding to the appropriate class I molecule (Nayersina et al.,

1993; Bertoletti et al., 1994; Couillin et al., 1995; and, Eisenlohr et al., 1992). Finally, as previously noted, the art teaches that the capacity of a putative CTL epitope to bind to a class I molecule does not mean that the epitope will be immunogenic (Nayersina et al., 1993; Couillin et al., 1995; and, Eisenlohr et al., 1992). The specification is silent concerning these caveats. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing and are attempting to capture subject matter to which they are clearly not entitled.

Non-statutory Double Patenting

5. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); and *In re Goodman*, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

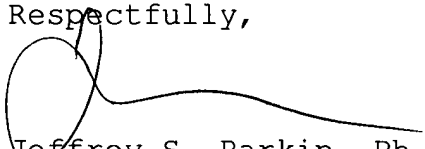
6. Claims 67-97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11-33 of U.S. Patent No. 5,709,995. Applicants have indicated that a terminal disclaimer will be submitted upon the identification of allowable subject matter.

Correspondence

7. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

8. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 September, 2002